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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,633	03/29/2004	James C. Patterson II	BIOD,002	2363

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EXAMINER	
LAMPRECHT, JOEL	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,633	PATTERSON, JAMES C.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 1-14, and 17 objected to because of the following informalities: Regarding claim 1, "data" in line 8 is misspelled, "the ratio", "the numerical index derived from the control subjects", and "said mean metabolic activity image data" all lack antecedent basis. Further, there lacks consistency between the recitation of claim 16, which sets forth that the normalized data is smoothed and the language of claim 1, which describes filtering, and then later recites "the normalized, smoothed data". Regarding claims 2 and 17 it is unclear what additional steps in the method have been presented. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the instant application, there is no sufficient tie to an apparatus (only that PET data needs to be collected from something) and no useful, concrete, tangible result is acquired ("index").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Becerra et al (US 6,907,280) in view of Deadwyler et al (US 2006/0276462 A1). Becerra et al disclose a method of producing an index of brain functionality using PET and other image data to show regional differences in brain activity, normalizing intensity data and filtering normalized data and locating regional extrema wherein activity rates are higher/lower than others (Col 4 Line 15-40, Col 23 Line 15-Col 24 Line 33). Becerra et al use Talairach space, transformations to Talairach space, smoothing functions and group comparisons both within different regions of the same brain, different times of the same region, and different statistical norms for regions of the brain (Col 23 Line 15-Col 24 Line 15). Normalized data can be normalized across subjects or within a subject to obtain a normal distribution of activity (Col 38 Line 1-Col 40 Line 25). These methods allow for the creation of volumes of interest within the brain for statistical and empirical analysis, including the calculation of mean intensity values (Col 38 line 55-65) within a region and the generation of parametric maps which can be used to show relative brain activity in regions compared to other regions and other subjects (Col 16 Line 8-Col 17 line 35, Col 8 Line 25-65, Col 28 Line 1-Col 34 Line 40, Claim 24, Figures 3a/b). These values are indications of significance of activity rates within specific regions of the brain, and are compared to standard measures to find statistical significance of the data (Col 23 Line 35-Col 24 Line 50).

Becerra et al disclose all that is listed above but do not mention a specific smoothing function, does not mention the division of data into four volumes of interest with increased metabolism activity and nine volumes with decreased metabolism, and therein does not specifically suggest normalizing the data set of increased metabolism by dividing the intensity values of the first set of volumes by a mean value of intensity of a second set of volumes of interest which have decreased metabolism, or dividing the intensity values of each of a set of volumes with increased metabolic activity divided by the mean value of the intensities of volumes of interest with increased metabolic activity. While those specific mentions of statistical analysis are not mentioned, Becerra et al do mention using mean intensity values for different statistical subsets and dividing other subsets by intensity values elsewhere and from previous scans to help with data normalization and statistically significance amongst data acquired. Weighted-mean intensity data is subtracted for normalization, rather than divided across the acquired data (Col 38 Line 55-65).

Becerra et al describe the use of volumetric analysis of volumes of interest by normalizing the intensity for the region, which is retained in Talairach space, and then levels of activity all across both regions of interest and regions which were not selected a priori for analysis but end up as statistically significant (Col 23 Line 15-Col 24 Line 15, Col 31 Line 11-55), statistical intensity values of volumes of interest are normalized, set to standards over a number of subjects, regions, and times (Col 28 Line 1-40, Col 30 Line 58 – Col 31 Line 11, Col 33 Line 26-Col 34 Line 40, Claims 8-16). Smoothing functions are used to correct for motion variance within data collected (Col 27 Line 58-

Col 28 Line 48, Col 38 Line 55-65). Becerra et al do not disclose the use of analysis with regard to a particular disease, but measure with respect to pain, and to find a link between psychiatric disease (Col 8 Line 65-Col 9 Line 30, Claim 7) and brain activity (response to drug interactions).

While not using the same specific techniques for statistical analysis, the methods provided by Becerra et al provide the basis for optimization of parameters and data values for incorporation into a diagnostic treatment and the optimization of parameters which would be well-known in the art, therefore it would have been obvious to one of ordinary skill in the art to have used the processing and statistical analysis of Becerra et al to provide a number of regions (they use 10) for statistical analysis and normalization *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Becerra et al do disclose all that is listed above, but do not collect resting PET data, and do not specifically mention how PET data acquisition, specifically in the case of glucose metabolism analysis is acquired. Attention is directed to the secondary reference by Deadwyler et al (US 2006/0276462 A1) which discloses in the background information that acquisition of PET data of resting patients has motivated further statistical analysis of response-driven testing since 1991 (0008). The monitoring of a patient while performing a task, or while a patient is resting changes the expected result, but not the method which is employed. Baseline PET data is acquired on days following rest and days of sleep deprivation (0217) for analysis of regional glucose metabolism changes. It would have been obvious to one of ordinary skill in the art at the time of the invention to have utilized the data-analysis methods of Becerra et al, with

the acquisition of PET data for analysis of FDG-PET image data disclosed by Deadwyler et al for the purpose of analyzing cognitive decline in patients (title, background).

Response to Arguments

Applicant's arguments filed 4/7/08 have been fully considered but they are not persuasive. Regarding the argument that Becerra et al does not disclose a method of producing a brain index using PET, Examiner disagrees. While Becerra et al focuses on the statistical analysis and processing with fMRI data, there is explicit mentioning of PET data acquisition as a perfectly-suitable alternative data acquisition modality for the same analysis procedures (Col 3 Line 25 - Col 4 Line 40). With regard to the argument that Becerra et al do not create weighted volumes of interest which are normalized for analysis, Examiner again disagrees with Applicant. As cited above, Column 28 Line 25 - Column 29 line 10 recites comparative signal evaluation, and standardization methods are disclosed from Col 38 Line 55-65. These analysis procedures show that normalization of image data and subsequent weighting is utilized for interpretation and analysis of the data, which would be performed as a medical practitioner would compare data. Examiner acknowledges that "resting" for an hour is disclosed within the specification; however, it is unclear how the state of the patient somehow defines the instant application over that of a procedure which acquires data from a patient with the methods disclosed above in both Deadwyler et al and Becerra et al as claimed. Further standard procedures for resting data acquisition are disclosed referentially in US

6,785,568 B2 to Britton Chance, and are noted as being pertinent to the instant application should the acquisition of data while at rest require further explanation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure includes 6,785,568 B2 to Chance which discloses a method for acquiring data from a patient while at rest, through a verbal command of "telling a subject to rest" (Col 21 Line 30-40).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JML